AUG 1 2001

K012299

Attachment I
510(K) Summary
BASIC Dental Implant System Straight Post and Core II Attachment

This 510(K) Summary of safety and effectiveness for the BASIC Dental Implant System Straight Post and Core II Attachment is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	BASIC Dental Implant Systems, Inc.
Address:	3321 Columbia NE Albuquerque, New Mexico 87107 USA
Contact Person:	Dan Blacklock, Vice-President
Telephone / Fax / Email	505.881.1376 – Phone 505.884.1923 – Fax
Preparation Date:	July 19, 2001
Device Trade Name:	BASIC Dental Implant System Straight Post and Core II Attachment
Common Name:	Accessory to a Dental Implant
Classification:	DZE
Legally Marketed Predicate Device:	BASIC Dental Implant System 2-Piece Post and Core Attachment K number K001259
Description of the Straight 2-Piece Post and Core Attachment:	The Straight Post and Core II Attachment is a three-piece attachment. The top is attached to the base with a hex screw. The base is cemented into a dental implant. Artificial teeth are then attached to the Straight Post and Core II using conventional techniques.
Intended use:	The Straight Post and Core II Attachment is intended to attach artificial teeth to a dental implant.
Performance Data:	None
Results of Clinical Study:	None
Conclusion:	The Straight Post and Core II attachment is substantially equivalent to other existing Straight 2-Piece Post and Core attachments in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Mr. Dan Blacklock
Vice President
Basic Dental Implant Systems, Incorporated
3321 Columbia, N.E.
Albuquerque, New Mexico 87107-2001

Re: K012299
Trade/Device Name: BASIC Dental Implant System Straight 2-Piece Post and Core Attachment
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: July 19, 2001
Received: July 20, 2001

Dear Mr. Blacklock :

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012299

INDICATION FOR USE STATEMENT

510(k) Number: ~~Pending~~ K012299

Device Name: BASIC Dental Implant System Straight 2-Piece Post and Core Attachment

Indications for Use:

The BASIC Dental Implant System Straight 2-Piece Post and Core Attachment is indicated for attaching artificial teeth to a dental implant.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012299